Exhibit #D 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is: K082617

JAN 15 2009

1. **Proposed Device**

Trade/Proprietary Name: Trauson General Spinal System (GSS)

Common Name: Pedicle screw spinal system

Classification Name:

Orthosis, Spondyloisthesis spinal fixation (MNH)

Orthosis, Spinal pedicle fixation (MNI)

Device Class: II

Product Code: MNH, MNI

Regulation Number: 21 CFR 888.3070

Intended Use:

Trauson General Spinal System (GSS) is intended for posterior pedicle screw fixation (GSS-VII can be applied for anterior or anterolateral fixation) of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities.

When used as a posterior spine thoracic/lumbar system, Trauson General Spinal System (GSS) is indicated for one or more of the following: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion (5) pseudarthrosis, (6) spinal stenosis.

Trauson General Spinal System (GSS) is not intended for pedicle screw fixation above T8.

2. **Sponsor Information**

TRAUSON (JIANGSU) MEDICAL INSTRUMENT CO., LTD.

31 Houcun Road, Niutang Town

Changzhou, Jiangsu, 213163, CHINA

Phone: +86-757-86280075

Fax: +86-757-86397179

Submission Correspondent

Ms. Diana. Hong, Mr. Lee. Fu

Shanghai Mid-link Consulting Co., Ltd.

Suite 8D, No.19, Lane 999, Zhongshan No.2 Road(S)

Shanghai, China, 200030

3. **Predicate Device**

PILOT™ Spinal System (K063601)

Device Name: PILOT™ Spinal System

Common Name: Pedicle screw spinal system

Classification Name:

21 CFR 878.3070

Pedicle Screw Spinal System

Product Code:

MNI: Orthosis, Spinal, Pedical Fixation

MNH: Orthosis, spondylolis thesis spinal fixation

Sponsor:

Life Spine

2400 Hassell Road, Suite 370

Hoffman Estates, IL 60195

Telephone: 847-884-6117

Fax: 847-884-6118

4. Device Description

The applicant device of Trauson General Spinal System (GSS) made of Titaniuim Alloy (Ti-6AL-4V) that meet ASTM 136 is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients.

The applicant devices are not provided sterile. The materials are wildly used in the industry with well know biocompatibility. No new materials are used in the development of this implant. No surface modified or coated.

All variants use the same material, same design principle and are constant thickness.

No chemical for the enhancement of its clinical performance is applied on or incorporated into applicant device.

5. Test Conclusion

Performance tests demonstrate that the specifications of the proposed device meet its design input.

6. Substantially Equivalence

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trauson (Jiangsu) Medical Instrument Co., Ltd.
% Shanghai Midlink Business Consulting Co., Ltd
Ms. Diana Hong
Lane 999, Zhongshan No. 2 Road Suite 8D, No 19
Shanghair
China

JAN 15 2009

Re: K082617
Trade/Device Name: Trauson General Spinal System (GSS)
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: November 19, 2008
Received: November 21, 2008

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

Exhibit # A Indication for Use

510(k) Number: K082617

Device Name: Trauson General Spinal System (GSS)

Indications for Use:

Trauson General Spinal System (GSS) is intended for posterior pedicle screw fixation (GSS-VII can be applied for anterior or anterolateral fixation) of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities.

When used as a posterior spine thoracic/lumbar system, Trauson General Spinal System (GSS) is indicated for one or more of the following: (1) trauma (i.e. fracture or dislocation), (2) curvatures (scoliosis, kyphosis, and/or lordosis), (3) spinal tumor, (4) failed previous fusion (5) pseudarthrosis, (6) spinal stenosis.

Trauson General Spinal System (GSS) is not intended for pedicle screw fixation above T8.

Prescription Use __√__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082617